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D. Remarks

Reconsideration and allowance of the present application in view of the accompanying remarks are respectfully requested.

Claims 1-4, 6-11 and 22-29 were pending in this application. and of those claims 1, 8, 22, 25 and 28 are independent. Of those claims, claims 25 - 29 are allowed. Independent claims 1, 8, and 22 are under rejection, and the discussion will focus primarily on these claims.

The Examiner rejected claims 1, 3, 7, 8, 10 and 22 as being allegedly anticipated by Klein ('284). The Examiner stated that Klein teaches an apparatus for radiation treatment of an internal body lumen. The Examiner stated that the Klein apparatus includes a balloon catheter **34** having an inflatable balloon **32** and a tube segment (radiation-emitting sleeve catheter **10**) that is adapted to be longitudinally slid over, carried by and cover the balloon. The Examiner stated that the tube segment **10** includes a radioactive material **30,302** that is mixed with a non-radioactive material **38** (col. 24, lines 65-67). The Examiner stated that the tube segment **10** can be an expandable and collapsible material, such that the tube segment is expandable in a range of sizes and the shape of the tube segment is determined by the shape of the balloon as the balloon inflates to expand the segment and deflates to collapse the segment. The Examiner stated that the embodiments of the tube segment **10** are formed of an elastomeric material that covers the balloon substantially entirely during inflation (col. 12, lines 35-39 and Figs. 5-6). The Examiner stated that the outer surface of the tube segment **10** is exposed to come into direct contact with the luminal

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structure. The Examiner stated that in operation, the balloon catheter **34** is inserted into the body lumen; the radioactive tube segment **10** is longitudinally slid over the balloon catheter **34** such that the tube segment including the radioactive material **30,302** is disposed over the balloon **32**; the balloon **32** is inflated with fluid to expand the tube segment **10** and administer a radiation dose to the luminal structure; the balloon **32** is deflated and the tube segment **10** collapsed; and the balloon catheter **34** and tube segment **10** are removed from the luminal structure.

The Examiner rejected claims 2 and 9 as being allegedly obvious over Klein ('284) in view of Hess ('168). The Examiner stated that Klein teaches all of the limitations of the claims except that the radioactive material is in the form of a coating on the tube segment. The Examiner stated that it is well known in the art that a non-radioactive material can be provided with radioactive characteristics by coating the non-radioactive material with a radioactive material. The Examiner stated that Hess teaches a stent **74** which is coated with a radioactive material in order to assist in preventing restenosis of an artery. The Examiner stated that it would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Klein by coating a tubular segment with a radioactive material in view of the teachings of Hess in order to produce a tube that is radioactive at its distal end.

The Examiner stated that claims 4 and 11 are rejected as being allegedly obvious over Klein ('284) in view of Lewis et al. ('552). The Examiner stated that Klein teaches all of the

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limitations of the claims except that the tube segment includes a non-radioactive material into which is absorbed radioactive material. The Examiner stated that Lewis et al. teach that it is known in the art to make intra-luminal radiation devices of a non-radioactive material into which is absorbed radioactive material. The Examiner stated that it would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Klein by absorbing radioactive material into a non-radioactive material in view of the teaching of Lewis et al. in order to produce a tube that is radioactive at its distal end.

The Examiner stated that claims 6, 23 and 24 are rejected as being obvious over Klein ('284) in view of Fischell et al. ('282). The Examiner stated that Klein teaches all of the limitations of the claims except that the tube segment is adhesively attached to the balloon and that the balloon is inflated with a gas. The Examiner stated that Fischell et al. teaches a catheter having an expandable radioactive source. The Examiner state that the catheter includes a balloon **14** with an expandable, elastic radioactive tube segment **16** adhesively attached to the balloon **14** by an outer balloon **15** which is heat sealed (shrunk) to the inner balloon (col. 5, lines 2-6). The Examiner stated that the balloon **14** is inflated with a carbon dioxide gas to bring the tube segment into proximity to a luminal structure (col. 6, lines 51-53). The Examiner stated that it would have been obvious to one having ordinary skill in the art that since the radioactive source **16** is expandable and elastic, the dosage per surface area of the source would inherently be different in an inflated state than that of the unexpanded state. The Examiner stated that it would have been obvious to one having

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ordinary skill in the art at the time Applicant's invention was made to adhesively attach the tube segment to the balloon of a radiation treatment device similar to that of Klein in view of the teachings of Fischell et al. in order to ensure proper positioning of the expandable radioactive tube segment with respect to the balloon. The Examiner stated that it further would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a carbon dioxide gas as an inflation medium in view of the teachings of Fischell et al. in order to inflate the balloon catheter of a device similar to that of Klein as an obvious engineering design choice, merely substituting one known inflation medium for another that is capable of performing the same function.

Without conceding the correctness of the Examiner's position, but solely to advance prosecution, independent claims 1, 8 and 22 are being amended to recite that the tube segment is substantially the same length as the balloon and has radioactive material substantially uniformly throughout its structure. Support for these amendments may be found in at least Fig. 3. Applicant believes that these claims now clearly distinguish over the Klein reference which does not directly or inherently disclose these features.

The Examiner has cited Figs. 5, 6, 11 and 12 for allegedly showing a tube segment formed of an elastomeric sleeve, and Figs. 7-10 for allegedly showing a sleeve of polymeric material having a plurality of folds.

It is the understanding of applicant that the portion of the device in the Klein reference to which the Examiner says is a

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tube segment is element 10. In Figs. 5, and 6, element 10 is a tube substantially longer than the length of the inflating balloon segment. Moreover, the radioactive elements 30 are arranged only intermittently around the circumference. In Figs. 11 and 12, the elements 30 (four of which are shown) are also arranged only intermittently. Claims 1, 8 and 22 recite that the radioactive material is substantially uniformly dispersed throughout the structure of the tube segment.

The other rejected claims are dependent either directly or indirectly on independent claims 1, 8 or 22, and are patentable for at least the same reasons that the independent claims are patentable. The other prior art fails to remedy the deficiencies of Klein stated above.

In view of the foregoing, applicants respectfully request withdrawal of the rejections of the pending claims and request allowance.

If a telephone interview would be of assistance in advancing prosecution of the subject application, the undersigned attorney invites the Examiner to telephone him at the telephone number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. If any fee is required, authorization is hereby given


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to charge the amount of any such fee to Deposit Account Number
03-3125.

Respectfully submitted,

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is being deposited this date with the
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